



United States
Department of
Agriculture

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Marketing and
Regulatory
Programs

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-02

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Subject: Diagnostic Test Kits for Bovine Spongiform Encephalopathy

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and permit applications for diagnostic test kits (including "rapid tests") intended as an aid in the diagnosis of bovine spongiform encephalopathy (BSE).

II. BACKGROUND

Numerous test methods (e.g., immunohistochemistry, ELISA, Western blot) and commercial test kits have been developed to aid in the diagnosis of BSE. Some of these kits have been approved by foreign regulatory officials (e.g., European Union, Japan) for use in their BSE testing programs. Due to recent confirmed cases of BSE in North America and the anticipated increase in surveillance for BSE in the U.S., the CVB will accept and consider license and permit applications for diagnostic test kits intended to aid in the diagnosis of BSE.

The CVB will proceed with the review and testing processes of each license or permit application up to the point of issuing the actual U.S. Veterinary Biological Product License or Permit. In the future, the CVB will issue additional guidance on the final U.S. Veterinary Biological Product License or Permit restrictions required for distribution and sale of these diagnostic test kits in the U.S.

III. ACTION

Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services (VS) Memorandum No. 800.50, Basic License Requirements for Applicants; VS Memorandum No. 800.101, U.S. Veterinary Biological Product Permits



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for Distribution and Sale; and VS Memorandum No. 800.73, General Requirements for Immunodiagnostic Test Kits, for guidance in applying for licensure. This information is available on the CVB website:

www.aphis.usda.gov/vs/cvb/regsandguidance.htm

Applications and supporting materials should be submitted to the CVB-Policy, Evaluation, and Licensing for review.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics